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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/762,224   | 07/30/2001  | David A. Sanders     | 7024-497PUR115      | 2859             |
| 26813  | 7590        | 04/07/2004           | EXAMINER            |                  |
| MUETING, RAASCH & GEBHARDT, P.A.<br>P.O. BOX 581415<br>MINNEAPOLIS, MN 55458 |             |                      | PARKIN, JEFFREY S   |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1648                |                  |

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |   |                                       |  |
|------------------------------|---|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/762,224        | <b>Applicant(s)</b><br>SANDERS ET AL. |  |
|                              | <b>Examiner</b><br>Jeffrey S. Parkin, Ph.D. | <b>Art Unit</b><br>1648               |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 13-18,30-32,39,44-52,54 and 55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12,19-29,33-38,40-43 and 53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>02102003/05292001</u> . | 6) <input type="checkbox"/> Other: _____  |

Serial No.: 09/272,262  
Applicants: Li, X., et al.

Serial No.: 09/762,224  
Applicants: Sanders, D. A., et al.

Docket No.: 7024-497P  
Filing Date: 07/30/01

## Detailed Office Action

### *Status of the Claims*

Applicants' election with traverse of Group I (claims 1-12, 19-29, 33-38, 40-43, and 53) in the communication filed 18 December, 2003, is acknowledged. The traversal is based upon the premise that examining all the inventions simultaneously would not constitute an undue burden on the examiner. The examiner does not concur with this assessment. The basis for the lack of unity finding was clearly set forth on page 2 of the last Office action. **The requirement is still deemed to be proper and is therefore made FINAL.** Claims 13-18, 30-32, 39, 44-52, 54, and 55 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.<sup>1</sup> Claims 1-12, 19-29, 33-38, 40-43, and 53 are currently under examination.

### *37 C.F.R. § 1.98*

The information disclosure statements filed 29 May, 2001, and 10 February, 2003, have been placed in the application file and the information referred to therein has been considered.

### *35 U.S.C. § 112, Second Paragraph*

Claims 1-12, 19-29, 33-38, 40-43, and 53 rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the

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<sup>1</sup> Applicants are advised that claim 54, which clearly depends from claim 52, should have been included in Group IV (claims 50, 52, and 54). Accordingly, this claim has been withdrawn as set forth *supra*.

subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

Concerning claims 1-12, 19-29, and 53, the claims are vague and indefinite for failing to clearly set forth the salient characteristics of the nucleic acid construct. For instance, claim 1 simply recites a eukaryotic cell comprising a first, second, third, and fourth nucleotide sequence. However, the claims fail to sufficient structural and functional limitations to enable the skilled artisan to ascertain the metes and bounds of the claimed invention. Are the four nucleotide sequences tandemly arranged on the same expression vector or are they present on different vectors? What is the precise structural relationships of these various sequences? Appropriate correction, as supported by the disclosure, is required.

Concerning claims 33-38 and 40-43, the salient characteristics of the pseudotyped retroviral particle should also be clearly set forth. It is also not readily manifest what constitutes a "desired protein" encoding sequence or a "desired ribonucleotide sequence". What features or properties of the protein or nucleic acid are "desired"? Appropriate correction, as supported by the disclosure, is required.

#### ***Correspondence***

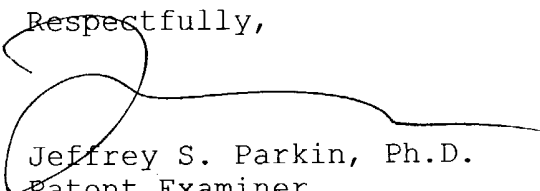
Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful,

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Serial No.: 09/272,262  
Applicants: Li, X., et al.

the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively.

Respectfully,



Jeffrey S. Parkin, Ph.D.  
Patent Examiner  
Art Unit 1648

02 April, 2004